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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/796,441 | 03/08/2004 | Michael Radomsky | DEPYP003D1C1 | 1814 |

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| EXAMINER | |
|---|---|
| HENRY, MICHAEL C | |
| ART UNIT | PAPER NUMBER |
| 1623 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 05/28/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@wavsip.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/796,441 | RADOMSKY, MICHAEL | |
| | Examiner | Art Unit | |
| | MICHAEL C. HENRY | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/12/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The following office action is a responsive to the RCE filed, 04/12/10.

The RCE filed 04/12/10 affects the application, 10/796,441 as follows: Upon further consideration it was determined that the notice of Allowance mailed 01/12/10 was not appropriate. Consequently, a new ground rejection is set forth herein below.

The responsive to applicants' amendment is contained herein below.

Claims 21-22 are pending in application.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanada et al. (EP 0 493 737) in view of Prisell et al.(Int. J. Pharmaceutics,1992, 85:51-56).

Hanada et al. disclose that bFGF can be used to treat bone disease (see page 2, paragraph [006] to [009], [012] to[016] and entire article). . Furthermore, Hanada et al. disclose that bFGF can accelerate bone formation (see page 2, paragraph [006] to [009], [012] to[016] and entire article). In addition, Hanada et al. disclose that bFGF can be topically administered to the disease site (see page 2, paragraph [006] to [009], [012] to[016] and entire article).

The difference between applicant's claimed method and the method taught by Hanada et al. is that Hanada et al. do not use hyaluronic acid in their composition.

Prisell et al. disclose that bone regeneration (bone growth) can be effected or stimulated by administration of a composition comprising IGF-1 (growth factor) in hyaluronic acid in which there is a slow release of IGF-1 by the composition (see page 55, left column, lines 20 to 41 and abstract). Furthermore, Prisell et al. disclose that hyaluronic acid which is a substance that occurs naturally in the body, can retard the release of peptide growth factors (which includes IGF-1 and bFGF) (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method suggested by Hanada et al. to treat promote or increase bone growth at the site of abnormal, injured or diseased bone by injecting or applying to the tissue site of said abnormal, injured or diseased bone a solution or liquid composition comprising an effective amount of a mixture of hyaluronic acid, the growth factor bFGF and excipients such as water (wherein the hyaluronic acid retards the release of bFGF sufficient to enhance, promote or increase bone growth) depending on factors such as the severity of the bone condition or disorder and the individual that is being treated.

One having ordinary skill in the art would have been motivated to use the method suggested by Hanada et al. to treat promote or increase bone growth at the site of abnormal, injured or diseased bone by injecting or applying to the tissue site of said abnormal, injured or diseased bone a solution or liquid composition comprising an effective amount of a mixture of hyaluronic acid, the growth factor bFGF and excipients such as water (wherein the hyaluronic acid retards the release of bFGF sufficient to enhance, promote or increase bone growth) depending on factors such as the severity of the bone condition or disorder and the individual that is being treated. It should also be noted that use of specific concentration of the components

(such as bFGF) of said composition also depending on factors such as the severity of the bone condition or disorder and the individual that is being treated. Also, it should be noted that it is obvious to alter parameters such as the viscosity of the composition in order to alter factors or properties such as the extent of retardation of the release of bFGF from the composition and consequently to optimize the enhancement, promotion or increase of bone growth, depending on factors such as the severity of the bone condition or disorder and the individual that is being treated.

Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagai et al.(Bone 1995. 16:367-373) in view of Prisell et al.(Int. J. Pharmaceutics,1992, 85:51-56).

Nagai et al. disclose that bFGF stimulates bone formation (bone growth) when administered to rats (see abstract, see also page 372, left col., last paragraph and entire article).

The difference between applicant's claimed method and the method taught by Nagai et al. is that Nagai et al. do not use hyaluronic acid in their composition.

Prisell et al. disclose that bone regeneration (bone growth) can be effected or stimulated by administration of a composition comprising IGF-1 (growth factor) in hyaluronic acid in which there is a slow release of IGF-1 by the composition (see page 55, left column, lines 20 to 41 and abstract). Furthermore, Prisell et al. disclose that hyaluronic acid which is a substance that occurs naturally in the body, can retard the release of peptide growth factors (which includes IGF-1 and bFGF) (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method suggested by Nagai et al to treat promote or increase bone growth at the site of abnormal, injured or diseased bone by injecting or applying to

the tissue site of said abnormal, injured or diseased bone a solution or liquid composition comprising an effective amount of a mixture of hyaluronic acid, the growth factor bFGF and excipients such as water (wherein the hyaluronic acid retards the release of bFGF sufficient to enhance, promote or increase bone growth) depending on factors such as the severity of the bone condition or disorder and the individual that is being treated.

One having ordinary skill in the art would have been motivated to use the method suggested by Nagai et al. to treat promote or increase bone growth at the site of abnormal, injured or diseased bone by injecting or applying to the tissue site of said abnormal, injured or diseased bone a solution or liquid composition comprising an effective amount of a mixture of hyaluronic acid, the growth factor bFGF and excipients such as water (wherein the hyaluronic acid retards the release of bFGF sufficient to enhance, promote or increase bone growth) depending on factors such as the severity of the bone condition or disorder and the individual that is being treated. It should also be noted that use of specific concentration of the components (such as bFGF) of said composition also depending on factors such as the severity of the bone condition or disorder and the individual that is being treated. Also, it should be noted that it is obvious to alter parameters such as the viscosity of the composition in order to alter factors or properties such as the extent of retardation of the release of bFGF from the composition and consequently to optimize the enhancement, promotion or increase of bone growth, depending on factors such as the severity of the bone condition or disorder and the individual that is being treated.

Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (Endocrinology 1995, 136: 1276-1284) in view of Prisell et al.(Int. J. Pharmaceutics,1992, 85:51-56).

Nakamura et al. disclose that bFGF stimulates bone formation (bone growth) when administered to rats (see abstract, see also page 1283, left col., 1st full paragraph and entire article). Furthermore, Nakamura et al. disclose that bFGF can be administered by injection (see abstract, see also page 1283, left col., 1st full paragraph and entire article).

The difference between applicant's claimed method and the method taught by Nakamura et al. is that Nakamura et al. do not use hyaluronic acid in their composition.

Prisell et al. disclose that bone regeneration (bone growth) can be effected or stimulated by administration of a composition comprising IGF-1 (growth factor) in hyaluronic acid in which there is a slow release of IGF-1 by the composition (see page 55, left column, lines 20 to 41 and abstract). Furthermore, Prisell et al. disclose that hyaluronic acid which is a substance that occurs naturally in the body, can retard the release of peptide growth factors (which includes IGF-1 and bFGF) (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method suggested by Nakamura et al. to treat promote or increase bone growth at the site of abnormal, injured or diseased bone by injecting or applying to the tissue site of said abnormal, injured or diseased bone a solution or liquid composition comprising an effective amount of a mixture of hyaluronic acid, the growth factor bFGF and excipients such as water (wherein the hyaluronic acid retards the release of bFGF sufficient to

enhance, promote or increase bone growth) depending on factors such as the severity of the bone condition or disorder and the individual that is being treated.

One having ordinary skill in the art would have been motivated to use the method suggested by Nakamura et al. to treat promote or increase bone growth at the site of abnormal, injured or diseased bone by injecting or applying to the tissue site of said abnormal, injured or diseased bone a solution or liquid composition comprising an effective amount of a mixture of hyaluronic acid, the growth factor bFGF and excipients such as water (wherein the hyaluronic acid retards the release of bFGF sufficient to enhance, promote or increase bone growth) depending on factors such as the severity of the bone condition or disorder and the individual that is being treated. It should also be noted that use of specific concentration of the components (such as bFGF) of said composition also depending on factors such as the severity of the bone condition or disorder and the individual that is being treated. Also, it should be noted that it is obvious to alter parameters such as the viscosity of the composition in order to alter factors or properties such as the extent of retardation of the release of bFGF from the composition and consequently to optimize the enhancement, promotion or increase of bone growth, depending on factors such as the severity of the bone condition or disorder and the individual that is being treated.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be

reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
May 19, 2010.

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623